DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-812/S-026

Parkdale Pharmaceuticals, Inc,
501 Fifth Street
Bristol, Tennessee 37620

Attention: Dean R. Cirotta
Senior Director, Regulatory Affairs

Dear Mr. Cirotta:

Please refer to your supplemental new drug application dated December 13, 1996, received December 16, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ketalar (ketamine hydrochloride injection, USP).

We acknowledge receipt of your submissions dated April 3, 1997, November 7, 2000, and January 31, 2001.

This supplement provides for revisions to the PRECAUTIONS, ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION, ANIMAL PHARMACOLOGY AND TOXICOLOGY sections and adds the DRUG ADUSE AND DEPENDENCE section to the package insert

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted January 31, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sara Shepherd, Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research